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January 25, 2024

**VIA ECF**

The Honorable Leda D. Wettre, U.S.M.J.  
United States District Court  
Martin Luther King, Jr. Federal Building  
50 Walnut Street, Room 2060  
Newark, New Jersey 07102

Re: *Axsome Therapeutics, Inc., et al. v. Teva Pharmaceuticals, Inc.*  
Civil Action Nos. 23-1695 (MEF)(LDW) & 23-23142 (MEF)(LDW)

Dear Judge Wettre:

This firm, together with Quinn Emanuel Urquhart & Sullivan LLP, represents Plaintiffs Axsome Therapeutics, Inc. and Antecip Bioventures II LLC (together, “Plaintiffs”) in the above-captioned related matters, which concern Plaintiffs’ claims against Defendant Teva Pharmaceuticals, Inc. (“Teva”) for patent infringement resulting from Teva’s submission of its Abbreviated New Drug Application (“ANDA”) for a generic version of Plaintiffs’ Auvelity® drug product. We write on behalf of all parties to (1) provide the status of Civil Action No. 23-1695 (the “First Case”) in advance of the February 1, 2024 status teleconference (see ECF No. 42), and (2) respectfully request consolidation of these two cases.

**I. Status of the First Case**

Plaintiffs initiated the First Case on March 24, 2023, alleging infringement of four patents listed in the FDA’s Orange Book for Auvelity® and for which Teva provided Paragraph IV certifications. According to the Pretrial Scheduling Order (ECF Nos. 30, 47), Plaintiffs served their infringement contentions and responses to Teva’s invalidity contentions on December 22, 2023,<sup>1</sup> and the parties are currently engaged in fact discovery, with both sides having served and responded to initial discovery requests.

**II. Consolidation Request**

Approximately nine months after Plaintiffs filed the complaint in the First Case, Plaintiffs filed Civil Action No. 23-23142 (the “Second Case”) on December 15, 2023, alleging

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<sup>1</sup> Pursuant to Your Honor’s January 12, 2024 Letter Order (ECF No. 49), Plaintiffs served their amended infringement contentions on January 12.

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infringement of three additional Auvelity® patents following receipt of Teva's November 2, 2023 Paragraph IV notice letter directed to those patents.<sup>2</sup> Shortly thereafter, Teva proposed that the parties move to consolidate these cases, and the parties then met and conferred and ultimately arrived at a mutually-agreeable case schedule that would accommodate the consolidation while also ensuring party and judicial economy (e.g., by obviating the need for duplicative depositions, serial *Markman* proceedings, and a second trial on related patents).

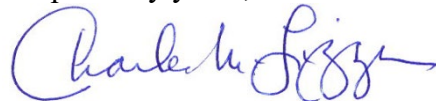
Accordingly, enclosed is a Proposed Consolidation Order to which the parties have agreed, which, subject to Your Honor's approval, would consolidate these cases for all purposes and extend the case schedule in the First Case by approximately six months to account for the consolidation. This extension will not increase the likelihood of emergent proceedings upon expiration of the August 10, 2025 30-month stay because, as Your Honor may recall from the Rule 16 conference in the First Case, the FDA cannot approve the current version of Teva's ANDA until at least November 5, 2034. If the Proposed Consolidation Order meets with the Court's approval, we respectfully request that Your Honor sign it and have it entered on the respective dockets to formally effect consolidation.

\* \* \* \*

The parties would be happy to further discuss these or any other issues that Your Honor would like to address during the February 1 status conference in the First Case. Otherwise, because there are no disputes ripe for the Court's consideration at this time, the parties would be amenable to an adjournment of the February 1 status conference until a date in late April, which, under the parties' Proposed Consolidation Order, is after Teva will serve its noninfringement and invalidity contentions for the patents asserted in the Second Case.

Thank you for Your Honor's kind attention to these matters.

Respectfully yours,



Charles M. Lizza

Enclosure

cc: All counsel of record (via email)

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<sup>2</sup> The patents, also listed in the FDA's Orange Book for Auvelity®, were not issued by the Patent Office until after Plaintiffs initiated the First Case.

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**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

**AXSOME THERAPEUTICS, INC. and ANTECIP  
BIOVENTURES II LLC,**

**Plaintiffs,**

**v.**

**TEVA PHARMACEUTICALS, INC.,**

**Defendant.**

Civil Action No. 23-01695  
(MEF)(LDW)

Civil Action No. 23-23142  
(MEF)(LDW)  
(consolidated)

(Filed Electronically)

**[PROPOSED] ORDER CONSOLIDATING CASES FOR ALL PURPOSES**

**WHEREAS**, Plaintiffs Axsome Therapeutics, Inc. (“Axsome”) and Antecip Bioventures II LLC (“Antecip” and, collectively with Axsome, “Plaintiffs”), filed Civil Action No. 23-01695 in this Judicial District against Defendant Teva Pharmaceuticals, Inc. (“Teva”) on March 24, 2023;

**WHEREAS**, Plaintiffs filed the related Civil Action No. 23-23142 in this Judicial District against Teva on December 15, 2023;

**WHEREAS**, Teva hereby acknowledges its acceptance of service of the complaint in Civil Action No. 23-23142;

**WHEREAS**, by agreement of the parties, Teva answered the complaint in Civil Action No. 23-23142 on January 18, 2024 (*see* ECF No. 11 in Civil Action No. 23-23142);

**WHEREAS**, Plaintiffs and Teva jointly request that Civil Action Nos. 23-01695 and 23-23142 be consolidated;

**IT IS** on this \_\_\_\_ day of \_\_\_\_\_, 2024,

**ORDERED** that Civil Action Nos. 23-01695 and 23-23142 (the “Consolidated Actions”) are consolidated for all purposes, including discovery, case management, and trial, subject to further order of the Court;

**IT IS FURTHER ORDERED** that all filings in the Consolidated Actions shall use the above caption on this Order;

**IT IS FURTHER ORDERED** that all filings going forward shall be filed in Civil Action No. 23-01695 and that Civil Action No. 23-23142 shall be administratively terminated by the Clerk’s office;

**IT IS FURTHER ORDERED** that the January 19, 2024 Letter Order setting the Initial Conference in Civil Action No. 23-23142 (ECF No. 13) is hereby vacated; and

**IT IS FURTHER ORDERED** that the Consolidated Actions shall proceed on the following amended schedule:

| <u>Event</u>  | <u>Deadline</u>   |
|---|-------------------|
| Plaintiffs’ Answer to Counterclaims<br>(’518, ’706, ’144 Patents Only)                                  | February 15, 2024 |
| Plaintiffs’ Disclosure of Asserted Claims under<br>L. Pat. R. 3.6(b)<br>(’518, ’706, ’144 Patents Only) | February 29, 2024 |

| <b><u>Event</u></b>  | <b><u>Deadline</u></b> |
|--|------------------------|
| Defendants' disclosure of Non-Infringement and Invalidity Contentions under L. Pat. R. 3.6(c)-(f) ('518, '706, '144 Patents Only)                      | April 18, 2024         |
| Plaintiffs' disclosure of Infringement Contentions and Responses to Invalidity Contentions under L. Pat. R. 3.6(g)-(i) ('518, '706, '144 Patents Only) | July 1, 2024           |
| Joint exchange of proposed claim terms under L. Pat. R. 4.1 (All Patents)  | July 12, 2024          |
| Preliminary proposed constructions and identification of intrinsic evidence under L. Pat. R. 4.2(a)-(b) (All Patents)                                  | July 25, 2024          |
| Joint exchange of all intrinsic and extrinsic evidence under L. Pat. R. 4.2(c) (All Patents)   | August 9, 2024         |
| Joint Claim Construction and Prehearing Statement under L. Pat. R. 4.3(a)-(e) (All Patents)  | August 28, 2024        |
| Close of Fact Discovery for Claim Construction (All Patents)   | October 4, 2024        |
| Opening Claim Construction Briefs (All Patents)  | October 18, 2024       |
| Close of Expert Discovery for Claim Construction (All Patents)   | November 15, 2024      |
| Responsive Claim Construction Briefs (All Patents)   | December 13, 2024      |
| Proposed schedule for <i>Markman</i> hearing due to Court  | January 3, 2025        |
| Close of Fact Discovery  | April 18, 2025         |

**SO ORDERED.**

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Hon. Leda D. Wettre, U.S.M.J.